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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,784	03/06/2002	Wayne M. Barnes	60019630-0038	9712

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,784	BARNES ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/26/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 1-7 and 14) in the reply filed on July 30, 2004 is acknowledged. Claims 8-13 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821. Claims 1-7 and 14 are rejected herein. This action is made NON-FINAL.

Sequence Notes

2. The Sequence Listing filed in this application complies with the requirements of 37 CFR 1.821-1.825 and has been entered.

Information Disclosure Statement

3. The information disclosure statement filed on September 26, 2002 complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered (see enclosed, signed PTO-1449).

Specification

4. The disclosure is objected to because of the following informalities:

A) On page 1, lines 4-5, Applicants should amend the specification to state, "This application claims priority from U.S. non-provisional application serial no. 09/920,872, now U.S. Patent Number 6,403,341..."

B) The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. See claims 4 and 6, for example.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 14 is drawn to an arrangement of printed matter, which is non-statutory subject matter, and therefore, is not patentable. See MPEP § 706.03(a) (stating, "For example, a mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See *In re Miller*, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967).")

Claim Interpretation

7. Given the broadest reasonable interpretation, Claim 1 has been interpreted as being drawn to a kit comprising a source of phosphate ions and a source of magnesium ions. See MPEP § 2111. The recitation of "wherein combining the source of magnesium ions and the source of phosphate ions form a precipitate at a temperature below 34⁰ C," does not limit the claim and does not distinguish the claimed invention from the prior art below. The claims are

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drawn to a product, and not to a method of combining sources of ions; therefore, the claims have not been interpreted as requiring a combination step. Furthermore, the combination of the source of magnesium ions and the source of phosphate ions (in the prior art below) are capable of forming a precipitate at a temperature below 34⁰ C.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Mirkin et al. (USPN 6,709,825).

Mirkin teaches a kit comprising a source of phosphate ions and a source of magnesium ions. See col. 120, lines 5-12, teaching a kit comprising magnesium chloride and a phosphate buffer.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usuda et al. (USPN 6,673,576) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment (1995)).

Usuda teaches a method of measuring the inosine-guanosine kinase activity of a transformed cell using a precipitate comprising a source of phosphate ions and a source of magnesium ions. See col. 15, lines 4-17, for example. Usuda does not teach packaging the source of phosphate ions and a source of magnesium ions in a kit.

However, Ahern teaches that pre-made reagents provided in kit form are convenient and save researchers time and money. See pages 3/5-4/5.

Accordingly, in view of the teachings of Ahern, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Usuda so as to have packaged the source of phosphate ions and a source of magnesium ions taught by Usuda et al into a kit. One of skill in the art would have been motivated to have made such a modification, in order to have provided practitioners the reagents

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needed to perform Usuda's measurement method, in a convenient format, for the advantages of efficiency and cost-effectiveness.

13. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al. (USPN 6,033,851) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment (1995)).

Yamane teaches a detection method comprising the use of a source of phosphate ions (e.g., phosphoric acid) and a source of magnesium ions (e.g., MgCl), at least two DNA polymerases, and dNTPs. See col. 6, for example.

Yamane does not teach packaging these reagents in a kit.

However, Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money. See pages 3/5-4/5.

Accordingly, in view of the teachings of Ahern, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Yamane so as to have packaged the source of phosphate ions and a source of magnesium ions taught by Yamane et al. into a kit. One of skill in the art would have been motivated to have made such a modification, in order to have provided practitioners the reagents needed to perform Yamane's detection method, in a convenient format, for the advantages of efficiency and cost-effectiveness.

14. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al. (USPN 6,033,851) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment (1995)), as applied to Claims 1-3, and in further view of Hyland et al. (USPN 5,972,602).

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The teachings of Yamane and Ahern are presented above and are incorporated herein.

The references teach the use of at least two DNA polymerases (e.g., the use of two Amplitaq reagents, which is a thermostable polymerase) for performing PCR. The references do not teach the DNA polymerases of Claim 4.

However, Hyland et al. teaches that Tth polymerase is a thermostable polymerase that is considered to be a functional equivalent of Amplitaq for use in a PCR assay, and therefore, it would be advantageous for the skilled artisan to use either Amplitaq or Tth polymerase in performing a PCR assay. See col. 3, lines 50-62. See also MPEP § 2144.06.

Accordingly, in view of the teachings of Hyland, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the kit of Yamane and Ahern so as to have packaged Tth polymerase in a kit, instead of Amplitaq, in order to have provided practitioners the reagents needed to perform an efficient PCR assay, in a convenient format, for the advantages of efficiency and cost-effectiveness.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al. (USPN 6,033,851) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment (1995)), as applied to Claims 1-3, and in further view of Barnes et al. (USPN 5,436,149).

The teachings of Yamane and Ahern are presented above and are incorporated herein.

The references teach using at least two DNA polymerases (e.g., the use of two Amplitaq reagents, which is a thermostable polymerase) for performing PCR. The references do not teach the use of at least two of the DNA polymerases of Claim 6.

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However, Barnes et al. teaches the use of at least two DNA polymerases of Claim 6, in order to extend “the applicable size range for efficient PCR,” and for “efficient and accurate PCR amplification of long DNA targets.” See col. 4, lines 1-11 and Example 6.

Accordingly, in view of the teachings of Barnes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the kit of Yamane and Ahern so as to have packaged at least two DNA polymerases of Claim 6 in a kit, in order to have provided practitioners the reagents needed to perform an efficient and accurate PCR assay of long DNA targets, in a convenient format, for the advantages of efficiency and cost-effectiveness.

Conclusion

16. No Claims are allowable.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

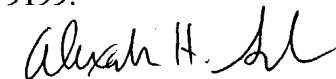
If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Alexander H. Spiegler
November 12, 2004



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